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VIA ECF

The Honorable Renée Marie Bumb
United States District Court Judge
District of New Jersey
Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets, Room 1050
Camden, NJ 08101

Re: *In re: Valsartan, Losartan, and Irbesartan Products Liability Litigation.*, U.S. District Court for the District of New Jersey; Case No. 1:19-md-02875

Dear Judge Bumb:

Teva Pharmaceuticals USA, Inc. ("Teva") respectfully submits this letter in further support of its October 29, 2024 letter [ECF 2916] outlining Teva's proposal to resolve the issues highlighted by the Court during the October 10, 2024 Case Management Conference ("CMC"), and in in reply to Plaintiffs' 30-page November 12, 2024 response letter [ECF 2921]. Plaintiff's response distorts the holding and import of the Third Circuit's recent decision in *Huertas v. Bayer US LLC*, No. 23-2178 (3d Cir. Nov. 7, 2024) (ECF 2921-1), and includes numerous mischaracterizations of Teva's proposals.

First, and contrary to Plaintiffs' assertion, *Huertas* is not "on all-fours with this litigation." ECF 2921 at 7. At most, the Third Circuit merely held in *Huertas*

that allegations that a product was so contaminated as to be rendered unusable suffice to plead Article III standing at the motion to dismiss stage.[1] The Third Circuit certainly did not hold, as Plaintiffs assert (six times in their letter) that an allegedly "contaminated" product is worthless "as a matter of law." ECF 2921 at 8, 10 n.7, 11, 15, 17. The parties here are far past the pleadings stage. This Court's effective exclusion of Professor Conti's opinions leaves no admissible evidence to support Plaintiffs' "worthlessness" theory, and Plaintiff has no evidence to support an alternative theory that the at-issue VCDs were "worth less."

Second, with respect to general causation, *Huertas* also did not hold that evidence of general causation is irrelevant in economic loss cases, as Plaintiffs wrongly assert. ECF 2921 at 28. Determining the value of the at-issue VCDs will require evaluating efficacy and risk, of which general causation is an essential component. Nothing in the *Huertas* opinion is inconsistent with Teva's proposal to conduct general causation Rule 702 hearings. *See* ECF 2916 at 5-7.

Third, Teva does not seek a "complete redo" of this litigation, as Plaintiffs insist. *See* ECF 2921 at 1-4. To the contrary, Teva seeks to move this litigation forward on the most efficient and logical path following the Court's recent rulings

[1] Even as to that point, there are important factual and legal differences between *Huertas* and this case, as discussed below.

excluding Professor Conti's proposed "worthlessness" opinions. *See* ECF 2916. Teva's summary judgment proposal does not require reconsideration of any prior rulings, let alone "nearly all major prior rulings in this litigation." ECF 2921 at 2.

Indeed, it is Plaintiffs that seek a "redo" as they ask "to supplement the TPP subclass expert record" and to "cure" Professor Conti's opinions with new damages theories. ECF 2921 at 22-26. Plaintiffs repeatedly attempt to justify their efforts to move backwards by asserting (ten times) that they relied upon the "law of the case," insisting that Judge Kugler's rulings at pre-trial stages (and before any Rule 702 hearing regarding Plaintiffs' damages evidence) somehow comprised a promise that Professor Conti's opinions must "go to the jury." *See id*. at 2, 3, 4, 5, 14, 17, 20, 22.

That is not the case. As discussed in Teva's initial letter, Judge Kugler recognized at each successive stage that his ruling was limited to that stage. ECF 2916 at 3-5; *see also* ECF 728 at 15; ECF 2261 at 89; ECF 2694. Judge Kugler's rulings conform to the Supreme Court's admonition to heed "the manner and degree of evidence required at the successive stages of the litigation." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992). Plaintiffs' ability to withstand challenges to their damages theory at earlier stages of the case—without the benefit of a Rule 702 hearing addressing Professor Conti's damages opinions—does not prevent this Court from evaluating whether triable claims remain following the Court's exclusion

of such opinions as unreliable.

A. Plaintiffs Mischaracterize the *Huertas* Decision.

Plaintiffs grossly overstate and at times outright misstate the holding in *Huertas*. The Third Circuit did not determine, as Plaintiffs erroneously and repeatedly state, that economic worthlessness damages are available "as a matter of law" where an alleged defect affects the product's intended use. ECF 2921 at 8, 10 n.7, 11, and 15. Rather, *Huertas* held that plaintiffs there had sufficiently alleged that the products at issue that were not usable were "worth less" as compared to the product manufactured without the defect. ECF 2921-1 at 10-11 ("We conclude that Plaintiffs have plausibly alleged that Lotrimin and Tinactin products that are unusable due to the contamination are necessarily worth less than the product when properly manufactured."). The issue in *Huertas* "turn[ed] on the first prong of the standing inquiry—whether Plaintiffs' complaint plausibly alleged injury-in-fact." *Id.* at 9 (emphasis added). In addition, the Third Circuit expressly refused to "decide whether contaminated products are necessarily worthless," or "how much less contaminated products are worth." *Id.* at 11, n.9. Accordingly, *Huertas* stands for the limited proposition that a benefit-of-the-bargain damages theory can clear the low bar for Article III standing sufficient to survive a motion to dismiss.

Plaintiffs nonetheless cherry-pick a handful of words and phrases from the

Huertas court's discussion of the Eleventh Circuit's ruling in *Debernardis v. IQ Formulations, LLC*, 942 F.3d 1076 (11th Cir. 2019), and mischaracterize the ruling as establishing "in no uncertain terms" that "economic worthlessness damages are available as a matter of law because the defect at issue is fundamental." ECF 2921 at 8; *see also id*. at 11, 15.[2] Plaintiffs even assert that a finding of adulteration is "legally dispositive" of worthlessness. ECF 2921 at 10. But *Huertas* says nothing at all about worthlessness damages being "available as a matter of law" for "a carcinogen-contaminated healthcare product previously sold and ingested" with "perhaps some residual health benefit[.]" ECF 2921 at 8. To the contrary, the Third Circuit stated: "We do not decide whether contaminated products are necessarily

[2] Plaintiffs repeatedly suggest that *Huertas* stands for the proposition that any contamination of a product is a "fundamental defect." (*See, e.g.*, ECF 2921 at 8, 10, 11, 13, 15, 16) (citing *Huertas* at 16). It does not. The only reference in *Huertas* to "defects" that "fundamentally affect the intended use of a product" is in a quote from *Debernardis*, as part of the discussion that such a theory is legally cognizable at the motion to dismiss stage. ECF 2921-1 at 16 (quoting *Debernardis*, 942 F.3d at 1085). *Huertas* does not endorse the view that every contamination is invariably a fundamental defect or invariably renders a product valueless. Plaintiffs' reliance on misrepresentation cases drawing analogies to "rhinestones sold as diamonds" underscores the point. ECF 2921 at 7-8 (quoting *FTC v. Figgie Int'l, Inc.*, 994 F.2d 595, 606 (9th Cir. 1993)). It makes sense that customers sold rhinestones as diamonds were defrauded and "should have the opportunity to get all their money back," *id.*, but that is not analogous to customers being sold a therapeutically effective drug with an unknown impurity. And the problem here is that Plaintiffs (and Professor Conti) have simply *asserted* a worthless product that delivered its anticipated therapeutic benefit without *proving* it.

'worthless,' as Plaintiffs allege. Having concluded that Plaintiffs' theory is viable, we need not determine precisely how much less contaminated products are worth." ECF 2921-1 at 11 n. 9.

Debernardis—which, like *Huertas*, and unlike the instant case, was decided at the motion to dismiss stage—also does not support imposition of "worthlessness" damages as a matter of law. According to the Eleventh Circuit, "[w]e accept, *at least at the motion to dismiss stage*, that a dietary supplement that is deemed adulterated and cannot lawfully be sold has no value." *Id.* (emphasis added).[3] The concurrence in *Debernardis* went on:

> At summary judgment, *each claimant will need evidence to back the point up*. Why was the product worthless to each of them? How did it deliver less than expected? Did each of them use the product even after they knew of the labeling deficiency? The answers to these questions and others will determine whether the case may proceed further and, if so, how.

[3] The Court recognized this critical distinction during the October 10, 2024 CMC, when discussing *Debernardis*. *See* ECF 2906 at 10:21-11:4 ("Chief Judge Bumb: No. And not to mention that that was on a motion to dismiss on top of it. So I think you got a problem there. . . . That's a motion to dismiss. So let me tell you why that's important, because on a motion to dismiss, I think it's very – here's the thing, is that, again, I keep going back to sugar pills. If at the end of the day the recall was because these were sugar pills which had no value, then I think it's a plausible argument because I think it can be supported by evidence that they had no value, zero value because they were sugar pills. *That's why the facts matter here*.") (emphasis added).

Id. at 1090 (Sutton, J., concurring) (emphases added).[4]

In short, neither *Debernardis* nor *Huertas* supports Plaintiffs' arguments that worthlessness damages are available as a matter of law based on a product recall—or suggests that the presence of contamination or alleged adulteration negates Plaintiffs' burden to present reliable evidence to support their damages theory. *Alleging* facts sufficient to survive a motion to dismiss is a far cry from having the admissible *evidence* required to sustain such a theory at trial. Here, Plaintiffs' damages theory failed at the evidentiary stage because it was premised entirely on Professor Conti's *ipse dixit* assertions of worthlessness, rather than a reliable valuation of the risks and benefits of VCDs to consumers who used and received a full therapeutic benefit from them.

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[4] Plaintiffs' suggestion (ECF 2921 at 18-20) that *Huertas*' reliance on *Debernardis* undermines Judge Rosenberg's summary-judgment decision in *Zantac* is particularly misplaced. Judge Rosenberg, too, relied on *Debernardis*—at the pleading stage, when she concluded that the plaintiffs had plausibly *alleged* standing but would need to back up that theory with *evidence* at future stages of litigation. *In re Zantac (Ranitidine) Prod. Liab. Litig.*, 546 F. Supp. 3d 1152, 1189 (S.D. Fla. 2021) (citing *Debernardis* majority and concurrence). As discussed below, the lack of *evidence* of economic harm following Judge Rosenberg's Rule 702 rulings is what animated her decision at the summary judgment stage. *See In re Zantac (Ranitidine) Prod. Liab. Litig.*, 2023 WL 4765409, at *13 (S.D. Fla. July 26, 2023) (distinguishing *Debernardis* on this basis); *infra* p. 13.

B. *Huertas* Is Factually Dissimilar to the Present Case.

Plaintiffs also gloss over factual dissimilarities between *Huertas* and the present case. In *Huertas*, the Third Circuit found that plaintiffs had plausibly alleged economic injury because the alleged contamination with benzene, a known "human carcinogen," rendered the products *unusable*. ECF 2921-1 at 6, 10-11, 12 & n.11. Although Plaintiffs repeatedly assert that the products in *Huertas* had been "previously sold and ingested" and "consumed or used," ECF 2921 at 7, 8; *see id.* at 5 ("*already-consumed*" (emphasis in original)), that again does not match all damages theories in *Huertas* or the ruling. The Third Circuit repeatedly referenced plaintiffs' allegations that their purchases were "unusable" and "cannot be used" because they were subject to a recall notice that instructed consumers to "stop using" their products. ECF 2921-1 at 10-12. Based on those specific allegations, the Third Circuit held that the plaintiffs had plausibly alleged standing:

> Contrary to Bayer's claim that 'Plaintiffs here do not allege that they stopped taking Lotrimin or Tinactin because they learned of the possibility that their products contained benzene,' . . . each Plaintiff alleges that he or she 'still had a portion' of their Lotrimin or Tinactin products and that they 'did not use and [were] unable to use the remaining portion[s]' of those products '*as a result* of [the] contamination.' App. 263–277. Construing these allegations in the light most favorable to Plaintiffs, they can plausibly allege they intended to use their products but were unable to do so 'as a result' of the benzene contamination.

Id. at 12 n.11 (emphasis in original).

Thus, the Article III standing holding in *Huertas* turned on the fact that the purported contamination allegedly rendered the product unusable and required that the product be discarded. Here, by contrast, Plaintiffs do not allege that they had to throw away VCDs because of the recalls, nor do they seek damages for replacement medications. To the contrary, Plaintiffs fully acknowledge they (or their insureds) used the recalled VCDs. In addition, Plaintiffs here allege that the "FDA advised patients to continue taking VCDs," because of the more immediate risks associated with "untreated" high blood pressure. *See* ECF 1708 at ¶ 425. Accordingly, this litigation is distinct from *Huertas*.

C. *Huertas* Did Not Hold that Evidence Relating to General Causation Is Irrelevant to Economic Loss Claims.

Plaintiffs do not discuss Teva's proposal to hold new Rule 702 hearings for general causation experts until the very end of their letter brief, where they again mischaracterize *Huertas* and wrongfully assert the Third Circuit held that evidence of general causation is not relevant in the context of an economic loss trial. ECF 2921 at 28 ("[T]he Third Circuit found that evidence of whether anyone actually got cancer from their use of Bayer's benzene-contaminated products is irrelevant in the context of an economic loss trial. . . . In other words, evidence relating to general causation is not relevant in the context of these class economic loss claims. It is the risk that matters in this context, not actual causation of cancer.") (citing ECF 2921-

1 at 16 n.14). Again, that is not what *Huertas* says. Footnote fourteen of *Huertas*, which is cited by Plaintiffs, merely states that "the economic injury addressed here is not for costs associated with adverse health consequences." ECF 2921-1 at 16 n. 14. This is not a suggestion, much less a holding, that general causation is irrelevant in the context of an economic loss trial. That is particularly so given that the Third Circuit was explicit in its declaration that it was not reaching the question of "how much less contaminated products are worth." *Id*. at 11 n.9. Because *Huertas* was decided at the pleading-stage case, the Third Circuit did not need to address the balancing of efficacy and risk that this Court identified as central to the valuation question—with general causation being an essential component of the risk side of that equation.

As this Court recognized, Plaintiffs' contention that "it is the risk that matters" and "not actual causation of cancer" (*see* ECF 2921 at 28) ignores the elephant in the room":

> Chief Judge Bumb: So I think you're talking yourself into the issue that I'm very concerned about.
>
> I think that what the plaintiff is trying to do is to have it both ways, is to stand up before this jury and say: 'These drugs should never have been sold, period. They have no value.'
>
> The plaintiffs want to phrase it in terms of a regulatory risk. I see no difference between a regulatory risk and a biological risk, but we'll get there. Because I think it then leaves a jury, you know, this elephant in

> the room with *risk of what*, without mentioning the word 'cancer,' and then tying the defendants' hands by not being allowed to prove it does not cause cancer.

ECF 2906 at 12:20-13:7 (emphasis added).

The Court was right in finding that the alleged risks of VCDs at issue in this litigation are inextricably tied to whether the medication causes cancer, and nothing in *Huertas* alters this analysis. Economic loss damages associated with a fully-consumed product require an assessment of risk and efficacy, which in turn requires an understanding of general causation. Moreover, Plaintiffs certainly cannot deny that general causation and the application of amended Rule 702 have significant implications as to the bellwether personal injury cases being readied for trial. Accordingly, hearings as to general causation experts under amended Rule 702 are another logical and efficient next step in these proceedings, regardless of whether the economic loss class action survives.

D. *Huertas'* Holding Does Not Conflict with the Court's Exclusion of Professor Conti's Opinions, Judge Kugler's Prior Rulings, or Judge Rosenberg's Management of the Zantac MDL.

The actual holding in *Huertas*—that the plaintiffs had sufficiently alleged the products at issue were "worth less" than properly manufactured products—does not conflict with the Court's exclusion of Professor Conti's "worthlessness" opinions here, nor with Judge Kugler's prior rulings. In *Huertas*, the Third Circuit found the

plaintiffs had sufficiently alleged the product was "worth less" than what they bargained for and did not reach the question of whether the product was "worthless," as the plaintiffs asserted. But this Court was presented with a very different set of circumstances in this litigation. Here, Plaintiffs sought to espouse a theory of economic "worthlessness"—i.e. that the medications had zero value. Although Judge Kugler previously ruled that such a theory had been sufficiently alleged at the pleading and class certification stages, he made clear that he was not adjudicating the viability of that theory on the merits. *See* ECF 728 at 15 (denying dismissal but noting "the constraints on our ability to subject Plaintiffs' claims to additional scrutiny *at this point*") (emphasis added)); *see also* ECF 775 at 20. It is also what he recognized at the class certification stage. *See* ECF 2261 at 89 (noting that "[a]t [the] class certification stage," the "methodology of an expert need not be perfect or even legally correct").

This Court recognized as much, explaining that the factual allegations necessary for a complaint to survive a motion to dismiss or the record required for class certification are not the same as the evidence necessary to get a claim to a jury.

> And from what I can gather from the record here, I think if I, you know, were to assess what Judge Kugler was thinking at the time, this was at the motion-to-dismiss stage. And so at summary judgment stage, *what he ruled was the plaintiffs will have to come forward and show through admissible evidence that it had zero value*.

> And saying it had zero value because it should never have been sold is strictly—*it's just argument revising history*. That's where I keep coming around. So I just don't know how—and that's what—that's the problem I had with Conti.

ECF 2906 at 30:20-31:5 (emphasis added).

This Court's reasoning also aligns with Judge Rosenberg's approach in the Zantac MDL. Although the *Zantac* court initially concluded that the plaintiffs had plausibly *alleged* economic injury-in-fact, the court later held at the summary judgment stage that plaintiffs had no admissible *evidence* to back up those allegations. S*ee supra* p. 7 n.4. The same is true here. At most, Plaintiffs plausibly alleged only a "worthless" theory, not a "worth less" theory—and they developed no *evidence* of a "worth less" theory through fact or expert discovery. Nor do they have any evidence to support their alleged "worthless" theory. Plaintiffs failed to put forth admissible evidence at the expert stage, with Professor Conti's "worthless" opinions effectively excluded by the Court. Plaintiffs likewise failed to offer evidence of the type of worthlessness evaluated in *Huertas*, for example, evidence that the VCDs were unusable (which would be at odds with Plaintiffs' allegations regarding the FDA's advisement to patients to continue taking recalled VCDs) *and in fact were not used*. *See* ECF 1708 at ¶ 425. It is Plaintiffs' burden to put up admissible evidence to substantiate their worthlessness theory, which they simply have failed to do. Accordingly, permitting summary judgment briefing on this issue

would be appropriate and consistent with *Huertas* and Judge Kugler's prior rulings.

E. Plaintiffs' Proposal, not Teva's, Seeks to Set Back the Litigation.

Although Plaintiffs accuse Teva of seeking a "redo," it is Plaintiffs that are seeking a do-over under the guise of a spurious "law of the case" argument and appeals to purported fairness. As noted above, Teva's request to brief summary judgment as to Plaintiffs' economic loss claim does not ask the Court to revisit any of Judge Kugler's rulings. The question now at hand is what remains of Plaintiffs' case in light of the exclusion of Professor Conti's opinions. The parties have litigated this case for many years, based on the economic worthlessness theory that Plaintiffs have made a strategic choice to advance as their sole damages theory. The deadlines to provide experts and evidence supporting these claims have long passed. And naturally, given this Court's rulings after Rule 702 hearings, Teva is seeking the opportunity to move for summary judgment on the claims in the TPP trial.

It is Plaintiffs, not Teva, who now want to set back the litigation by changing their damages theory and damages expert, as outlined in Teva's initial submission. *See* ECF 2916 at 3-4. Plaintiffs are forthright about this in their response, insisting they should be afforded a chance "to supplement the TPP subclass expert record" and to "cure" Professor Conti's opinions with new damages theories and opinions because they relied upon Judge Kugler's rulings as law of the case. ECF 2921 at 22-

26. But Judge Kugler emphasized at each successive stage that he had merely found Plaintiffs cleared the hurdles necessary at that stage—reserving the trial issues for trial. *See* ECF 2916 at 3-5; ECF 728 at 15; ECF 2261 at 89; ECF 2694. It is Plaintiffs, not Judge Kugler, that made the decision to go all-in on one damages theory in an effort to facilitate certification of a class. Holding them to the consequences of their strategic choices is not a departure from the law of the case; it is proceeding to the completion of the course Plaintiffs set for themselves.

Teva's proposal—and its goal—would move this litigation forward on the most efficient path. Teva respectfully requests that the Court permit summary judgment briefing at this stage, and set Rule 702 hearings on general causation experts. Teva stands ready to proceed to trial on any claims that survive summary judgment as the Court deems fit.

Sincerely,

/s/ Gregory E. Ostfeld
Gregory E. Ostfeld

cc: All counsel of record (via ECF)